

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 6 and 57-61 under 35 U.S. C. §112, first paragraph as not enabled, except for a colon cancer antigen and a nucleotide of SEQ ID NO:4. Applicants respectfully traverse the rejection.

As described in the specification and Examples, four of the nucleic acids referenced in the claims (SEQ ID NOs:1-4) were identified using SEREX methodology. The SEREX method uses antibodies found in cancer patient sera to clone sequences that encode proteins recognized by the antibodies. In the case of each of the polypeptides encoded by SEQ ID NOs:1-4, the specification teaches that these polypeptides were reactive with autologous and allogeneic cancer serum, but not with normal serum, therefore identifying the polypeptides encoded by SEQ ID NOs:1-4 as cancer-associated antigens (see Example 5, page 9, lines 4-7).

Additionally, Applicants submit that the application provides support for the identification of SEQ ID NO:5 as a cancer-associated molecule. Example 6 identifies SEQ ID NO:5 as a splice variant of SEQ ID NO:4 and provides tissue localization data indicating that SEQ ID NO:5 is associated with cancer. The specification at page 10, lines 19-21 describes the determination of expression of SEQ ID NO:5 in tissues and indicates that although SEQ ID NO:5 was not found to be expressed in normal pancreatic, liver, lung, heart fetal brain, mammary gland, bladder, and adrenal gland tissue, it was determined to be expressed in other tissues including cancerous tissues. The specification at page 6, lines 3-8, indicates that SEQ ID NO:5, like SEQ ID NO:4, was found to be expressed in colon tumor, colon metastasis, gastric cancer, renal cancer and colon cancer cell lines Colo 204 and HT29, as well as in normal colon, small intestine, brain, stomach, and testis. Thus, SEQ ID NO:5 is expressed in and associated with cancer.

In addition, Applicants also respectfully submit that because Applicants provide SEQ ID NO:5, Applicants have enabled the polypeptide encoded by SEQ ID NO:5 regardless of its pattern of expression.

Applicants assert on the basis of the arguments provided above, that each of the nucleic acids referenced in the claims has been shown to have an association with cancer, and that the application provides more than adequate support for the identification of SEQ ID NOs:1-5 as cancer-associated molecules. Thus, Applicants respectfully assert that claims 6, and 57-61 are

fully enabled and Applicants request the Examiner reconsider and withdraw the rejection made under 35 U.S.C. §112, first paragraph.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejections and act favorably upon the claims.

Respectfully submitted,



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Docket No. L00461.70081.US

Date: December 5, 2002

X12/24/02